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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/453,109	12/02/1999	MARK R. PRAUSNITZ	BVTP-P01-539	2183
28120	7590	04/04/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			KREMER, MATTHEW J	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/453,109

Applicant(s)

PRAUSNITZ ET AL.

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-23 is/are allowed.
- 6) ☒ Claim(s) 1,9,11,14-19,25,31,35 and 37-46 is/are rejected.
- 7) ☒ Claim(s) 2-8,10,12,13,24,26-30,32-34 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/3/2005 has been entered.

### ***Terminal Disclaimer***

2. The terminal disclaimer filed on 3/3/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,503,231 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Objections***

3. Claims 19 and 43 are objected to because of the following informalities. In claim 19, line 1, "one or more" should be inserted before "microneedles". In claim 43, line 1, "43" should be "42". Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 9, 11, 14-15, 25, 31, 35, 37, 40-41, and 44-46 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,848,991 to Gross et al. (Gross '991). Gross '991 teaches a device with a needle 14 that has a length up to 1 mm and a width of about 100 microns, a substrate 2a, and at least one reservoir 10. (column 7, lines 23-50 of Gross '991). It is noted that the limitation "for collecting a sample of a biological fluid" in the preamble was not given any patentable weight and was not considered a limitation since the body of the claim fully and intrinsically sets forth all of the limitations of the claimed invention and the preamble merely states the purpose or intended use of the invention rather than any distinct definition of any of the claimed invention's limitations. See MPEP 2111.02. It is further noted that the reservoir 10 is considered the collection chamber because there is no structural difference between the claimed collection chamber (a chamber that holds a fluid) and the reservoir of Gross (a chamber that also holds fluid). In regard to claim 9, there is a plurality of compartments since there is reservoir 10 and chamber 12. (Fig. 3 of Gross '991). In regard to claim 11, an adhesive layer 6 is disclosed. (Fig. 3 of Gross '991). In regard to claims 14-15

and 31, a sensor 28 is disclosed, which is in communication with the microneedle since the sensor controls the dispensing of the drug through the needle. (column 8, lines 6-8 and Fig. 3 of Gross '991).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,848,991 to Gross et al. (Gross '991) as applied to claim 15, and further in view U.S. Patent 5,722,397 to Eppstein. Gross '991 teaches that a blood glucose sensor is used. (claim 23 of Gross '991). Gross '991 does not teach the particulars of the blood glucose sensor. Eppstein teaches a blood glucose sensor (Fig. 7A-B of Eppstein) that would fulfill the requirements of providing a blood glucose sensor as set forth by Gross '991. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the glucose sensor of Eppstein in the invention of Gross '991 since Gross '991 teaches the use of a glucose sensor and Eppstein teaches one such sensor.

8. Claims 38-39 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,848,991 to Gross et al. (Gross '991) as applied to claim 1 and 15, and further in view U.S. Patent 5,807,375 to Gross et al. (Gross '375). Gross '991 teaches the use of a delivery needle but does not teach the material of the needle. Gross '375 teaches that such needles are made of platinum-iridium (Abstract of Gross '375), which would fulfill the requirements of providing a needle material as required by Gross '991. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use platinum-iridium as disclosed in Gross '375 since a needle material is required and Gross '375 teaches one such material.

***Allowable Subject Matter***

9. Claims 2-8, 10, 12-13, 24, 26-30, 32-34, and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 20-23 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 2, the prior art does not teach or suggest a means for inducing transport of a biological fluid or component thereof into the collection chamber that is combined or combinable with the other limitations of claim 2. In regard to claim

10, the prior art does not teach or suggest the use of a plurality of needles that is combined or combinable with the other limitations of claim 10. In regard to claim 13, the prior art does not teach or suggest a fracturable or removable barrier that is combined or combinable with the other limitations of claims 13. In regard to claim 20, the prior art does not teach or suggest that at least one of the microneedles is or comprises a sensor that is combined or combinable with the other limitations of claim 20. In regard to claim 24, the prior art does not teach or suggest that the collection chamber is adapted to receive and use glucose strips that is combined or combinable with the other limitations of claim 24. In regard to claim 26, the prior art does not teach or suggest a material to modulate the flow of biological fluid through the microneedles into the collection chamber that is combined or combinable with the other limitations of claim 26. In regard to claim 27, the prior art does not teach or suggest a step of triggering the means for inducing to permit the transport of a quantity of the biological fluid or an analyte therein through the microneedles and into the collection chamber that is combined or combinable with the other limitations of claim 27. In regard to claim 32, the prior art does not teach or suggest a means for inducing transport of the biological fluid or an analyte therein into the collection chamber that is combined or combinable with the other limitations of claim 32.


### ***Response to Arguments***

12. Applicant's arguments with respect to claims 1, 9, 11-12, 14-19, 25, 31, 35 and 37-46 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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Art Unit 3736

  
ERIC F. WINAKUR  
PRIMARY EXAMINER